REMARKS

In the Office Action dated February 26, 2003, the Patent Office required restriction between the following groups:

I Claim 10;

II: Claim 20;

III. Claims 21-22;

IV. Claim 23;

V. Claim 24; and

VI. Claim 25.

Applicants hereby elect the subject matter of Group II, with traverse with respect to Group VI (claim 25).

Amendments to the Claims

This amendment cancels claims 10, 21-24 that were not elected or traversed by Applicants. Applicants reserve the right to pursue the non-elected subject matter in a subsequent divisional application(s).

Additionally, this amendment cancels claim 20 and adds new claim 26, which is directed to the subject matter of elected group II, i.e., a method for predicting a haplotype pair for the Interleukin 4 Receptor Alpha(IL4Rα) gene of an individual, and new claims 27-29, which depend from claim 26. Claim 26 focuses the elected method by identifying the individual's genotype for the polymorphic sites in the haplotype pairs determined for the reference population described in the instant application. Support for new claim 26 may be found in claim 20 as originally filed and in the specification at p. 51, lines 17-18 and lines 25-26, and Table 4 on p. 69. Dependent claims 27-29 specify how various steps of the elected method are performed. Support for new claim 27, directed to the assigning step in independent claim 26, is found in the specification at p.52, lines 17-24. Support for new claims 28 and 29, directed to the identifying step of independent claim 26, is found in the specification at p. 49 line 13 through p. 51, line 16. Applicants respectfully assert that the added claims do not add new matter and their entry is respectfully requested.

Traversal of the Restriction Between Group II and Group VI

Applicants respectfully request that Group VI (claim 25), which is directed to a method of haplotyping an individual's IL4Rα gene, be rejoined with elected Group II (claims 26-29), which is directed to a method for predicting the haplotype pair for an individual's IL4Rα gene.

The Office Action has required restriction between the subject matter of these two groups of claims that it states are distinct inventions. MPEP §808.02 states that in order to establish that restriction between

distinct inventions is proper one of the following must be shown by appropriate explanation: (A) separate classification thereof; (B) a separate status in the art when they are classifiable together; or (C) a different field of search. The Office Action has relied upon reason (A), classifying the method claims of each of these groups into two different classifications, and reason (C), requiring different fields of search, for restricting the claims. The classification assigned to Group II is class 702, subclass 19 while the classification for Group VI is class 435, subclass 6. As elaborated below, the Office Action has failed to establish a prima facie case that Group II and Group VI may be restricted based on reason (A) or reason (C).

If a restriction requirement relies on reason (A), the requirement must provide an appropriate explanation as to why "each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search." (MPEP §808.02) However, the Office Action has failed to provide a *prima facie* case supporting the divergent classifications of the two Groups because it has failed to provide an explanation as to why the classification given to each of the method claims of Groups II and VI is appropriate for that group of claims. Indeed, assignment of the subject matter of the method claims of elected Group II to class 702, subclass 19, rather than to the same class assigned to the subject matter of Group VI (class 435, subclass 6), is not supported in the office action by any explanation at all.

The subject matter of Group II is drawn to a method of predicting a haplotype pair for the IL4Rα gene of an individual, while Class 702 covers Data processing: Measuring, Calibrating, or Testing. Class 702 provides for apparatus and corresponding methods wherein the data processing system or calculating computer is designed for or utilized in an environment relating to a specific or generic measurement system, a calibration or correction system, or a testing system. Subclass 19, Biological or Biochemical, indented under Subclass 1, "Measurement System in a Specific Environment", provides for subject matter wherein the data processing system or calculating computer is designed for or utilized in a measurement system directed to an environment of life or chemical compound or process in a living system. (See Manual of Patent Classification (MPC), Class 702, Subclasses 1 and 19) However, the class definition further indicates that for claims classified within subclasses of this class, such as Subclass 19, involving data processing for a measurement system in a specific environment, there must be "significant claim recitation of the data processing system, process or calculating computer". (MPC, Class 702, Section I.A.) The claims of Group II do not include significant recitation of the data processing system or calculating computer, and thus are inappropriately assigned to Class 702, subclass 19.

In contrast, the Office Action classified the very similar subject matter of claim 25 in Class 435, Subclass 6, which is indented under Subclass 4 and thus provides for a "Measuring Or Testing Process Involving Enzymes Or Microorganisms; Composition Or Test Strip Therefore; Processes Of Forming Such Composition Or Test Strip" (See MPC, Class 435, Subclasses 4 and 6). Applicants note they don't understand this classification since the scope of claim 25 is not limited to a measuring or testing process involving an enzyme or microorganism (e.g., a hybridization probe could be used to genotype one or more

polymorphic sites to determine the haplotype). However, if the Patent Office finds that this classification is appropriate for claim 25, then Applicants assert that it would be just as appropriate to classify the subject matter of independent claim 26 in the same way, although the method of independent claim 26 also does not require use of an enzyme or microorganism. Indeed, the objective of the method of haplotyping of claim 25, determining whether an individual has one or more haplotypes in Table 5, will in fact be achieved by performing the haplotype pair prediction method of independent claim 26. The specification (at page 52, lines 17-29) indicates to the reader what the skilled practitioner would know: that the method of haplotype pair prediction (claim 26) is simply one indirect method of haplotyping an individual (claim 25). Because of this close relationship between the subject matter of claim 25 with that of claim 26, these claims should in fact have the same classification and thus a restriction based on separate classification is improper.

The Office Action also relied on an alleged need to search different fields as a basis for requiring restriction between the claims of Group II and Group VI. However, the only apparent explanation for this allegation is the unsupported different classification of the two Groups, which as demonstrated above is improper. Thus, Applicants respectfully assert that the Office Action failed to establish a *prima facie* case that a separate field of search is indeed required for the two Groups.

Indeed, Applicants submit that a separate field of search should not be required to examine claims 25 and 26-29 for novelty and nonobviousness. The method of claim 25 is drawn to a method of haplotyping an individual comprising determining whether the individual has one or more of the haplotypes in Table 5. The method of claim 26 is directed to a method for predicting a haplotype pair of an individual comprising identifying a genotype for the individual at each of the polymorphic sites in the haplotype pairs in Table 4 and assigning a haplotype pair to the individual that is consistent with the data. Each of the IL4Rα haplotypes in the Table 5 recited in claim 25 is present in one or more of the IL4Rα haplotype pairs in the Table 4 recited in claim 26. Since each of these IL4Rα haplotypes and IL4Rα haplotype pairs involve the same human gene, the same genomic backbone structure, the same set of 39 polymorphic sites, and the same set of 53 haplotypes, Applicants respectfully assert that the same sources of prior art (e.g., scientific literature on the IL4Rα gene, sequence databases, polymorphism databases, and the like) would need to be searched and have not been able to imagine what types of prior art sources would be relevant to searching one claim and not the other. Applicants respectfully assert that the Patent Office may not maintain a restriction between claims 25 and claim 26 based on different literature and sequence searches without stating *how* they would be different.

As established above, Claims 25 and 26 may not be properly restricted based on separate classification (Reason A) or different fields of search (Reason C), the reasons relied upon in the Office Action. Furthermore, Applicants respectfully assert that these claims may not be restricted based on a separate classification in the art when they are classifiable together (Reason B of MPEP §808.02).

For a restriction requirement to rely on reason (B), the requirement must provide an appropriate explanation that even "though they are classified together, each subject can be shown to have formed a separate subject for inventive effort". (MPEP §808.02) The method of claim 25 is drawn to a method of haplotyping an individual comprising determining whether the individual has one or more of the haplotypes in Table 5. A haplotype, as defined in the instant application, is a phased 5′ to 3′ sequence of nucleotides found at a set of polymorphic sites in a locus on a single chromosome from a single individual. The method of claim 26 is directed to a method for predicting a haplotype pair of an individual comprising identifying a genotype for the individual at each of the polymorphic sites in the haplotype pairs in Table 4 and assigning a haplotype pair to the individual that is consistent with the data. Each of the haplotype pairs in Table 4 comprises one or two of the haplotypes in Table 5. Determination of the haplotypes in Table 5 and the haplotype pairs in Table 4 found in the reference population based on the genotypes of individuals in that population was achieved by a single inventive effort by the Applicants. Consequently, claims 25 and 26, drawn to methods of haplotyping the IL4Rα gene in an individual and predicting the haplotype pair for the IL4Rα gene in an individual, respectively, do not have separate status in the art and may not properly be restricted based on reason (B).

The MPEP at §808.02 states that where "classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions." As demonstrated above, claims 25 and 26-29 should have the same classification, these claims have the same status in the art, and do not require different fields of search. Moreover, since the method of haplotype pair prediction (claim 26) is simply one indirect method of haplotyping an individual (claim 25), there is no clear indication of cause for separate future classification or separate field of search for these claims. Thus, restriction between claims 25 and 26 for examination purposes is improper and rejoinder of claim 25 with elected Group II (claims 26-29) is requested.

It is believed that no additional fees for claims are due, however if that is incorrect, Applicants hereby authorize you to debit deposit account 50-1293.

Should any questions arise, or if Applicants' Agent can facilitate examination of this application, it is respectfully requested that the undersigned Agent be contacted so that any remaining issues can be resolved.

Respectfully submitted,

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